Pharmacy Benefit Coverage Criteria

Effective Date..... 8/1/2025
Coverage Policy Number P0050

HIV Products

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

This coverage policy addresses the use of HIV Products covered under the pharmacy benefit. The use of intravenous ibalizumab-uiyk is not addressed in this coverage policy.

This policy addresses the following for Employer Group plans: [follow link to section]

I. **The list of HIV Products Requiring Prior Authorization is contained within Appendix 1:** [follow link to section] **Prior authorization criteria for these products are listed below unless otherwise specified.**

HIV Products are considered medically necessary for the treatment of HIV infection when ANY of the following criteria are met:

- Individual is less than 13 years of age
- Individual is pregnant
- Individual is established on an HIV product
- Individual is not a candidate (for example, drug-drug interactions, drug-disease interactions, resistance) for **FIVE** preferred single tablet complete regimens (multi-ingredient formulations):
    - For example*, Biktarvy, Dovato, efavirenz/lamivudine/tenofovir disoproxil fumarate (generic Symfi/Symfi Lo), Genvoya, Symtuza, Triumeq

***Coverage for products varies across plans. Refer to the customer's benefit plan document for coverage details**

Specific Prior Authorization Criteria apply for the following products:

A. Tenofovir Disoproxil Fumarate (TDF)

I. Tenofovir Disoproxil Fumarate tablet is considered medically necessary when ONE of the following criteria are met:

- Treatment of HIV
- HIV Preexposure Prophylaxis (PrEP)
- HIV Postexposure Prophylaxis (PEP)
- Treatment of Hepatitis B

II. Non-Covered HIV Products (table below):

Employer group plans may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review. Cigna approves coverage for these drugs or biologics as medically necessary when sufficient information demonstrates that the clinical criteria set forth below are met. Unless otherwise stated, all Covered Alternative Drugs are required prior to the approval of the non-covered drug or biologic.

Non-Covered HIV Products	Standard Drug List Plan Performance Drug List Plan (Not Covered [NC])	Value Drug List Plan Advantage Drug List Plan/Cigna Total Savings Plan (Not Covered [NC])	Legacy Drug List Plan (Prior Auth. [PA] Required)
Atripla	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Atripla		
Combivir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Combivir		
Crixivan®	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on indinavir sulfate (Crixivan) o Not a candidate for other antiretroviral agents		
darunavir propylene glycolate 600 mg, 800 mg tablet	Criteria is met by the following: • Documented trial of **darunavir ethanolate** (generic for Prezista) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.		
didanosine/didanosine delayed-release	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on didanosine/DR (Videx/Videx EC) o Not a candidate for other antiretroviral agents		
Emtriva capsule	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Emtriva		
Epivir®	Criteria is met by the following:		

	• Documented intolerance to (1) generic formulation of Epivir
Epzicom™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Epzicom
Intelence	Criteria is met by the following: Documented intolerance to (1) generic formulation of Intelence
Kaletra™ oral solution **Kaletra™** tablet	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Kaletra
Lexiva™ tablet	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Lexiva
Prezista® 600mg, 800mg tablet	Documented trial of **darunavir tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Norvir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Norvir
Rescriptor®	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on delavirdine mesylate (Rescriptor) o Not a candidate for other antiretroviral agents
Retrovir® capsule, solution, syrup, tablet	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Retrovir
Reyataz® capsule	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Reyataz
Selzentry 150mg, 300mg tablet	Documented trial of **maraviroc tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
stavudine	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on stavudine o Not a candidate for other antiretroviral agents
Sustiva®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Sustiva
Symfi	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Symfi
Symfi Lo	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Symfi Lo
Trizivir®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Trizivir
Truvada®	Criteria is met by the following: • Documentation that individual has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, is likely to result in a significant allergy or serious adverse reaction or is otherwise medically inappropriate
Videx®/Videx® EC	Criteria is met by the following: • For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following: o Established treatment on didanosine/DR (Videx/Videx EC) o Not a candidate for other antiretroviral agents

Viracept®	Criteria is met by the following:
	• For treatment of human immunodeficiency virus type 1 (HIV-1) and **EITHER** of the following:
	  ○ Established treatment on nelfinavir mesylate (Viracept)
	  ○ Not a candidate for other antiretroviral agents

Viramune®	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Viramune
Viramune® XR™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Viramune XR

Viread® 300 mg tablet	Criteria is met by **BOTH** of the following:
	• **ONE** of the following:
	  • Treatment of HIV
	  • HIV Preexposure Prophylaxis (PrEP)
	  • HIV Postexposure Prophylaxis (PEP)
	  • Treatment of Hepatitis B
	• Documented intolerance to (1) generic formulation of Viread

Ziagen™	Criteria is met by the following: • Documented intolerance to (1) generic formulation of Ziagen

Initial and reauthorization is up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Other uses of HIV Products not addressed in the above criteria are considered experimental, investigational, or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indications

Drugs@FDA:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

Background

OVERVIEW

Approximately 1.2 million individuals ≥ 13 years of age in the US have HIV infection.[1] Among these individuals, approximately 65% receive some HIV care, 50% are retained in care, and 57% are virally suppressed or undetectable. Viral suppression or undetectable viral load not only protects the health of the individuals with HIV, but there is also a preventative benefit. Patients with HIV who take antiretroviral therapy (ART), as prescribed, and achieve and maintain undetectable viral load can live healthy lives and will not transmit HIV to an HIV-negative partner.

Antiretrovirals (ARVs) are used for the treatment of HIV infection in adults and children.[1] The ARVs have also been used for the prevention of HIV acquisition following occupational or non-occupational exposure in the post-exposure prophylaxis setting (PEP and nPEP, respectively) and for the prevention of HIV acquisition among high-risk uninfected individuals (pre-exposure prophylaxis [PrEP]). Three products are indicated in heavily treatment-experienced adults with multidrug resistant HIV (Rukobia [fostemsavir extended-release tablets], Sunlenca [lenacapavir subcutaneous injection and tablets], and Trogarzo [ibalizumab-uiyk intravenous injection]).

GUIDELINES

The DHHS provides guidelines for the management of HIV in adults and adolescents, in pediatric patients, and during the perinatal period.[2-4] In addition, ARVs have been used for PrEP and occupational PEP as well as nPEP; published guidelines on these topics are also available.[6-9,11] Guidelines are updated frequently and should be consulted for the most up-to-date information. The International Antiviral Society (IAS)-USA Panel generally makes similar first-line recommendations for ARV-naïve adults with HIV-1 to the DHHS guidelines.[16]

Appendix 1*

[follow link to Cigna for Health Care Professionals drug look up list for individual customer information]

HIV Products Requiring Prior Authorization
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)
abacavir
Emtriva™**
lamivudine
Retrovir®**
tenofovir disoproxil fumarate**
Viread®**
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)
Edurant®
efavirenz
nevirapine
Pifeltro™
Protease Inhibitors (PIs)
Aptivus®
Fosamprenavir
Invirase®
Lexiva™**
Reyataz®**
Fusion Inhibitors
Fuzeon®
CCR5 Antagonists
Maraviroc
Selzentry®
Integrase Inhibitors
Isentress® HD
Combination HIV Medicines
abacavir/lamivudine
abacavir/lamivudine/zidovudine
Cimduo™
Complera®
Delstrigo™
emtricitabline/rilpivirine/tenofovir disoproxil fumarate tablet
Evotaz®
Odefsey®
Prezcobix®
Stribild®
Temixys™

**Certain products, strengths, formulations may not be covered; see Non-Covered HIV Products table. [follow link to section]

*If you're a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

References

1. US statistics. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics. Updated September 28, 2022. Accessed on October 12, 2022.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Department of Health and Human Services. September 21, 2022. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed on October 12, 2022.
3. Panel on Antiretroviral Therapy and Medical Management of HIV-infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection. Last updated: October 11, 2022. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-arv/guidelines-pediatric-arv.pdf. Accessed on October 18, 2022.
4. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-Infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Last updated: March 17, 2022. Accessed on October 18, 2022.
5. US Public Health Service. Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2021 update. A clinical practice guideline. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Accessed on October 18, 2022.
6. Kuhar DT, Henderson DK, Strubble KA, et al for the US Public Service Working Group. Updated US Public Health Services guidelines for the management of occupation exposures to human immunodeficiency virus and recommendations for post exposure prophylaxis. *Infection Control and Hospital Epidemiology*. 2013;34(9):875-892. Update May 23, 2018. Available at: https://stacks.cdc.gov/view/cdc/20711. Accessed on October 18, 2022.
7. Centers for Disease Control and Prevention. US Department of Health and Human Services. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. Available at: http://stacks.cdc.gov/view/cdc/38856. Update May 23, 2018. Accessed on October 18, 2022.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed on October 18, 2022.
9. Isentress® film-coated tablets, chewable tablets, and oral suspension and HD tablets [prescribing information]. Whitehouse Station, NJ: Merck; May 2021.
10. Complera® tablets [prescribing information]. Foster City, CA: Gilead: November 2019.
11. Prezcobix® tablets [prescribing information]. Titusville, NJ: Janssen: April 2022.
12. Evotaz® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb: July 2020.
13. Dutrebis™ tablets [prescribing information]. Whitehouse Station, NJ: Merck: February 2015.
14. Triumeq® tablets [prescribing information]. Research Triangle Park, NC: ViiV: June 2023.
15. Delany-Moretwle S, Hughs JP, Back P, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase III, randomized clinical trial. *Lancet*. 2022;339:1779-1789.
16. Saag MS, Gandhi RT, Hoy J, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
17. Tivicay® tablets and Tivicay PD tablets for oral suspension [prescribing information]. Research Triangle Park, NC: ViiV/GlaxoSmithKline; October 2022.
18. Apretude® extended release intramuscular injection (suspension) [prescribing information]. Research Triangle Park, NC: ViiV; December 2021
19 Genvoya® tablets [prescribing information]. Foster City, CA: Gilead; January 2022.
22. Odefsey® tablets [prescribing information]. Foster City, CA: Gilead; September 2021.
23. Pilkington V, Hughes SL, Pepperrell T, et al. Tenofovir alafenamide vs. tenofovir disoproxil fumarate: An updated meta-analysis of 14,894 patients across 14 trials. *AIDS*. 2020;34:2259-2268.
24. SymfiLo™ tablets [prescribing information]. Morgantown, WV: Mylan; October 2019.
25. Cimduo™ tablets [prescribing information]. Morgantown, WV: Mylan; February 2021.
26. Symfi™ tablets [prescribing information]. Morgantown, WV: Mylan; October 2019.
27. Landovitz RJ, Donnell D, Clement ME, et al; for the HTPN 083 Study Team. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med*. 2021;385;595-608.
28. Biktarvy® tablets [prescribing information]. Foster City, CA: Gilead; October 2022.
29. Stribild® tablets [prescribing information]. Foster City, CA: Gilead; September 2021.

30. Symtuza® tablets [prescribing information]. Titusville, NJ: Janssen; April 2022.
31. Dovato® tablets [prescribing information]. Research Triangle Park, NC: ViiV Healthcare and GlaxoSmithKline; October 2022.
32. US Preventative Services Task Force. Preexposure prophylaxis for the prevention of HIV infection US Preventative Services Task Force Recommendation Statement. *JAMA*. 2019;21(22):2203-2213.
33. Truvada® tablets/oral powder [prescribing information]. Foster City, CA: Gilead; June 2020.
34. Centers for Disease Control and Prevention (CDC). HIV surveillance report. Last reviewed February 28, 2022. Available at: https://www.cdc.gov/hiv/statistics/overview/index.html. Accessed on October 18, 2022.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Added** generic emtricitabline/rilpivirine/tenofovir disoproxil fumarate tablet to Appendix 1.	8/1/2025

The policy effective date is in force until updated or retired.